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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,327	02/24/2004	Paul J. Sheskey	63633	9686
109 7590 03/14/2012 The Dow Chemical Company P.O. BOX 1967 2040 Dow Center Midland, MI 48641				
EXAMINER				
HELM, CARALYNNE E				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
03/14/2012		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

FFUIMPC@dow.com

Office Action Summary**Application No.**

10/785,327

Applicant(s)

SHESKEY ET AL.

Examiner

CARALYNNE HELM

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 21-26 and 28 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 21-26 and 28 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-SB-03)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

To summarize the election of record, applicant elected Group I drawn to processes for dispersing fluids in a mass of solid powder particles.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le et al. (US PGPub No. 2003/0181501) in view of Larson et al. (WO 00/18871 – US Patent No. 6,682, 042 referenced as English equivalent) as evidenced by Parikh (Handbook of Pharmaceutical Granulation Technology. Ed. Parikh Marcel Dekker Inc.: New York 1997 p 1) and Hoy et al. (US Patent No. 6,506,409).

Le et al. teach the granulation of particles of the drug valdecoxib which has extremely low water solubility (10 µg/ml) and meets the limitation of a water insoluble therapeutic agent (see paragraph 5, example 9 and instant specification page 12 line 31-32). A granulation method is taught where a powder composed of valdecoxib, the binder Avicel PH101, and a disintegrant are combined with a granulation fluid that includes water, the non-polymeric surfactant sodium lauryl sulfate, and no binder (see table 8 G5 and Hoy et al. column 3 lines 33-35; instant claims 21 and 28). The granulation fluid is sprayed on top of and mixed with the particles (see paragraph 135; instant claims 23 and 28). After granulation, the granules are pressed into a tablet thus indicating that they are capable of being pressed into a tablet without a coating step (see paragraph 137; instant claim 21). The size of the final product is assessed and has

an average size that is smaller than 500 micrometers (see table 9; instant claims 24-26). Given that a granulation process by definition results in the collection of small particles into larger masses (e.g. agglomerates), the starting powder must also have an average particle size that is smaller than 1000 micrometers (see Parikh page 1 paragraph 1; instant claims 21 and 28). Le et al. do not teach that the granulation fluid is applied as a foam.

Larson et al. teach that in comparison with conventional granulating fluids, granulation foams are able to generate a much more homogenous distribution through the bed of particles (see column 3 lines 11-16). This then yields more efficient wetting, the need for less granulating fluid, less drying, a more homogeneous particle size as well as the avoidance of over granulation (see column 3 lines 17-23). As in Le et al. the granulation fluid of Larson et al. preferably employs water as the diluent and includes a surfactant to be distributed through a bed of particles (see column 3 lines 1-6 and column 8 lines 30-34). Air is employed as the gaseous medium added to the granulating fluid to generate the foam (see column 9 lines 33-35; instant claims 21 and 28). When applied to a bed of particles the foam is applied without atomizing and mixed with mixer blades (see column 17 lines 19-29; instant claims 22 and 28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Le et al. such that their granulating fluid is foamed with air (yielding an water-based air-foam) prior to its application to the bed of particles so as to gain the improvements discussed by Larson et al. This modification would have been obvious as the application of the same technique to a similar method ready for

improvement to yield predictable results. It then follows that application of the foam without atomization on top of the particles as Larson et al. also teaches would also have been obvious. Therefore claims 21-25 and 28 are obvious over Le et al. in view of Larson et al. as evidenced by Parikh and Hoy et al.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Le et al. in view of Larson et al. as evidenced by Parikh and Hoy et al. as applied to claims 21-25 and 28 above, and further in view of Hardie-Muncy et al. (previously cited).

Le et al. in view of Larson et al. as evidenced by Parikh and Hoy et al. render obvious the method of instant claim 21. Various proportions of water are employed in the granulating medium that is employed such as 84 wt% and 69 wt% (see table 1 G1 and table 8 G5 as calculated by the examiner). The modified reference does not explicitly teach that water is included in the foamed granulating medium at 99.99 to 90 weight percent.

Hardie-Muncy et al. teach the agglomeration of edible particulate materials by whipping a coating medium into a foam then applying the foam to this powder so as to agglomerate them (see abstract and column 1 lines 5-11). The foamed composition is taught to contain water at 80% to 99.9% and preferably 91% to 96% (see column 2 lines 33-38).

As a foamed granulating composition employed to granulate edible particles, as in Le et al. in view of Larson et al., it would have been obvious to one of ordinary skill in the art to look to the teachings of Hardie-Muncy et al. to help guide the selection of the

proportion of water for a foamed version of the granulating medium of Le et al. in view of Larson et al. as evidenced by Parikh and Hoy et al. Since the foamed form has a preference for higher water content, it would have been obvious to select a proportion at the higher end of the taught range. Therefore claim 26 is obvious over Le et al. in view of Larson et al. and Hardie-Muncy et al. as evidenced by Parikh and Hoy et al.

Response to Arguments

Applicant's arguments filed January 4, 2012 have been considered. The previous grounds of rejection are hereby withdrawn in light of the amendment to the claims. In regards to the rejection made under 35 USC 112 second paragraph, the recitation of a granulation process results in the agglomeration of particles, by definition. Therefore the later recitation of the process encouraging or promoting agglomeration of particles is in essence a generalized restatement of limitations that are already present and as a result do not make the claim indefinite. New grounds of rejection are presented that address the claims in their current form, therefore the arguments provided by the applicants directed to the withdrawn rejections are moot.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634